

**510(k) SUMMARY****BÂRRX Medical's HALO<sup>90</sup> Coagulation System****Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared:**

BÂRRX Medical Inc.  
540 Oakmead Parkway  
Sunnyvale, CA 94085

Phone: (408) 328-7302  
Facsimile: (408) 328-7395

Contact Person: Viorica Filimon

Date Prepared: January 20, 2006

**Name of device and Name/Address of Sponsor:**

HALO<sup>90</sup> Coagulation System  
HALO<sup>90</sup> Coagulation Catheter  
HALO<sup>90</sup> Coagulation Generator

BÂRRX Medical Inc.  
540 Oakmead Parkway  
Sunnyvale, CA 94085

**Common or Usual Name(s):**

Electrosurgical Coagulation System

**Classification Name:**

Product code: GEI  
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories  
Device Class: II  
Classification panel: General & Plastic Surgery

## **Predicate Device(s)**

**K051168 HALO<sup>360</sup> Coagulation System-BARRX Medical Inc.**

**K050831 Stellartech Coagulation System 2-Stellartech Research Corporation**

## **Intended Use / Indications for Use**

The HALO<sup>90</sup> Coagulation System intended use is for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract.

The HALO<sup>90</sup> Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

## **Technological Characteristics**

The HALO<sup>90</sup> Coagulation System consists of the HALO<sup>90</sup> Coagulation Generator with a disposable single-use HALO<sup>90</sup> Coagulation Catheter, output cable, and an optional footswitch. The HALO<sup>90</sup> Coagulation System performance and mode of operation is substantially equivalent to the already cleared HALO<sup>360</sup> Coagulation System and Stellartech Coagulation System 2.

## **Substantial Equivalence**

The HALO<sup>90</sup> Coagulation System and the predicate devices: HALO<sup>360</sup> Coagulation System and Stellartech Coagulation System 2 have the same or similar intended use, indications for use, technological characteristics, and principles of operation. The technological differences between the HALO<sup>90</sup> Coagulation System and its predicates are: (1) use of an endoscope and pivot mechanism for electrode positioning; (2) elimination of the sizing balloon and the need to select a custom size coagulation catheter; (3) additional materials; and (4) minor modification of the generator software to support the changes in the catheter design. All these differences were evaluated on bench and did not raise questions regarding safety and efficacy. Thus the devices are equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

APR 21 2006

Ms. Viorica Filimon  
Vice President of Quality/Regulatory Affairs  
BARRX Medical, Inc.  
540 Oakmead Parkway  
SUNNYVALE CA 94085

Re: K060169  
Trade/Device Name: HALO<sup>90</sup> Coagulation System  
Regulation Number: 21 CFR §878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: January 20, 2006  
Received: January 27, 2006

Dear Ms. Filimon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

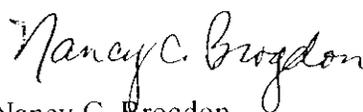
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K060169

Device Name: HALO<sup>90</sup> Coagulation System

Indications for Use:

The HALO<sup>90</sup> Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Prescription Use X  
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device System Evaluation (ODE)

Jane C. Brogden  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K060169

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